AMENDMENT TO H.R. 6378

OFFERED BY M__. _____

[Page/line numbers refer to posted draft dated July 13, 2018]

Page 6, line 8, strike ''no later than every two years'' and insert ''not less than annually''.

Page 7, line 25, strike ''is amended'' and insert '', as amended by subsection (a)(1)(C), is further amended''.

Page 8, line 14, strike ''and''.

Page 8, after line 21, insert the following:

''(v) development of clinical guidance for use of medical countermeasures; and

''(vi) postmarket evaluation of the safety and efficacy of medical countermeasures used pursuant to an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act.

Page 9, line 20, strike ''may'' and insert ''shall''.

Page 9, line 24, through page 11, line 15, amend subsection (b) to read as follows:

(b) MEMBERS.—In addition to the Assistant Secretary for Preparedness and Response, who shall serve as chair, the PHEMCE shall include the following members:

(1) The Director of the Biomedical Advanced Research and Development Authority (or the Director's designee).

(2) The Director of the Centers for Disease Control and Prevention (or the Director's designee).

(3) The Director of the National Institutes of Health (or the Director's designee).

(4) The Commissioner of Food and Drugs (or the Commissioner's designee).

(5) The Secretary of Defense (or the Secretary's designee).

(6) The Secretary of Homeland Security (or the Secretary's designee).

(7) The Secretary of Agriculture (or the Secretary's designee).

(8) The Secretary of Veterans Affairs (or the Secretary's designee).

(9) The Secretary of State (or the Secretary's designee).

(10) The Director of National Intelligence (or the Director's designee).

(11) The Director of the Central Intelligence Agency (or the Director's designee).

(12) Representatives of any other Federal agencies, as the Assistant Secretary for Preparedness and Response determines appropriate.

Page 24, lines 23 and 24, strike ''Pandemic and All-Hazards Preparedness Reauthorization Act of 2018'' and insert ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018''.

Page 26, strike lines 5 through 16.

Page 26, line 17, strike ''(f)'' and insert ''(e)''.

Page 29, line 6, strike ''15'' and insert ''25''.

Page 30, line 8, insert ''geriatric'' before ''medical''.

Page 30, line 13, insert ''geriatric'' before ''disaster''.

Page 31, line 1, insert ''and 2811D'' after ''2811B''.

Page 31, line 5, insert ''and 2811D'' after ''2811B''.

Page 31, line 14, strike ''dual or''.

Page 31, line 15, insert '', individuals with disabilities,'' after ''children''.

Page 32, lines 2 through 3, strike ''**IN ALL-HAZARDS EMERGENCIES**'' and insert ''**AND DISASTERS**''.

Page 32, lines 9 through 10, strike ''**IN ALL-HAZARDS EMERGENCIES**'' and insert ''**AND DISASTERS**''.

Page 32, lines 24 through 25, strike ''all-hazards'' and insert ''public health''.

Page 34, line 4, strike subparagraph (G) (and make such conforming changes as may be necessary).

Page 43, line 13, insert ''or public health emergency'' after ''incident''.

Page 49, after line 18, insert the following new section (and make such conforming changes as may be necessary):

SEC. 117. GRANTS TO STUDY AND REDUCE HEALTH CARE ACQUIRED INFECTIONS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

''SEC. 399V–7. GRANTS TO STUDY AND REDUCE HEALTH CARE ACQUIRED INFECTIONS.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities to study and reduce health care acquired infections that occur in hospital settings.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a), an entity shall be a health care system that has—

''(1) extensive experience in—

''(A) treating patients to full recovery from a high-consequence pathogen such as Ebola; and

''(B) teaching and training health care professionals in a health care setting; and

''(2) a plan to assess, not later than three years after the date on which the entity receives such a grant, how such grant impacts how health care professionals are trained and evaluated.

''(c) USE OF FUNDS.—Grants awarded under this section to an eligible entity shall be used—

''(1) to conduct evidence-based health care research on reducing the transmission of health care acquired infections that occur in hospital settings, specifically targeting interprofessional providers, including nurses, physicians, laboratorians, environmental services, food services, facilities, and health care administration; and

''(2) to support the four strategic goals of the Department of Health and Human Services relating to—

''(A) strengthening health care;

''(B) advancing scientific knowledge and innovation;

''(C) advancing the health, safety, and well-being of the people of the United States; and

''(D) ensuring efficiency, transparency, accountability, and effectiveness of programs.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2019 through 2023.''.

Page 52, lines 12 and 13, strike ''Pandemic and All-Hazards Preparedness Reauthorization Act of 2018'' and insert ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018''.

Page 53, lines 4 and 5, strike ''Pandemic and All-Hazards Preparedness Reauthorization Act of 2018'' and insert ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018''.

Page 54, before line 1, insert the following (and make such conforming changes as may be necessary):

(A) in clause (vi), by inserting '', including public health agencies with specific expertise

that may be relevant to public health security, such as environmental health agencies,'' after ''stakeholders'';

Page 54, strike line 19, through page 55, line 2 and insert the following:

''(II) the plans that utility companies within the entity's jurisdiction have in place to ensure that utilities will remain functioning or return to functioning as soon as practicable during outages caused by natural or manmade disasters;''.

Page 55, after line 16, insert the following new subsection (and make such conforming changes as may be necessary):

(b) EXCEPTION RELATING TO APPLICATION OF CERTAIN REQUIREMENTS.—Section 319C–1(g) of the Public Health Service Act (42 U.S.C. 247d–3a(g)) is amended—

(1) in paragraph (5)—

(A) by striking ''Beginning with fiscal year 2009'' and inserting ''Beginning with fiscal year 2019'';

(B) by striking ''for the immediately preceding fiscal year'' and inserting ''for either of

the two immediately preceding fiscal years''; and

(C) by striking ''2008'' and inserting ''2019''; and

(2) by amending subparagraph (A) of paragraph (6) to read as follows:

''(A) IN GENERAL.—The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in section 319C–1 or 319C–2:

''(i) For each of the first two fiscal years immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5) by the entity, an amount equal to 10 percent of the amount the entity was eligible to receive for each such fiscal year.

''(ii) For each of the first two fiscal years immediately following two consecutive fiscal years in which an entity experienced such a failure, an amount equal to 15 percent of the amount the entity was eligible to receive for each of such first two fiscal years, disregarding any withholding

of funds that would have been made in each such year by virtue of clause (i). The amount determined pursuant to the previous sentence shall be in lieu of any amount that would have been withheld for each such year by virtue of clause (i).

''(iii) For each of the first two fiscal years immediately following three consecutive fiscal years in which an entity experienced such a failure, an amount equal to 20 percent of the amount the entity was eligible to receive for each of such first two fiscal years, disregarding any withholding of funds that would have been made in each such year by virtue of clauses (i) and (ii). The amount determined pursuant to the previous sentence shall be in lieu of any amount that would have been withheld for each such year by virtue of clauses (i) and (ii).

''(iv) For each of the first two fiscal years immediately following four consecutive fiscal years in which an entity experienced such a failure, an amount equal to 25 percent of the amount the entity was el-

igible to receive for each of such first two fiscal years, disregarding any withholding of funds that would have been made in each such year by virtue of clauses (i), (ii), and (iii). The amount determined pursuant to the previous sentence shall be in lieu of any amount that would have been withheld for each such year by virtue of clauses (i), (ii), and (iii).''.

Page 58, strike line 3 through 5 (and make such conforming changes as may be necessary).

Page 58, line 16, through page 61, line 13, strike subparagraphs (B) and (C) (and make such conforming changes as may be necessary).

Page 61, after line 13, insert the following (and make such conforming changes as may be necessary):

(9) in subsection (j)(1), by striking ''$374,700,000 for each of fiscal years 2014 through 2018'' and inserting ''$264,600,000 for each of fiscal years 2019 through 2023''.

Page 63, lines 16 through 23, amend section 205 to read as follows (and make such conforming changes as may be necessary):

SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SITUATIONAL AWARENESS AND BIOSURVEILLANCE CAPABILITIES.

(a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE CAPABILITIES.—Section 319D (42 U.S.C. 247d–4) is amended—

(1) in the section heading, by striking ''**REVITALIZING**'' and inserting ''**FACILITIES AND CAPACITIES OF**'';

(2) in subsection (a)—

(A) in the subsection heading, by striking ''FACILITIES; CAPACITIES'' and inserting ''IN GENERAL'';

(B) in paragraph (1), by striking ''and improved'' and inserting '', improved, and appropriately maintained'';

(C) in paragraph (3), in the matter preceding subparagraph (A), by striking ''expand, enhance, and improve'' and inserting ''expand, improve, enhance, and appropriately maintain''; and

(D) by adding at the end the following:

''(4) STUDY OF RESOURCES FOR FACILITIES AND CAPACITIES.—Not later than June 1, 2022, the Comptroller General of the United States shall conduct a study on Federal spending in fiscal years

2013 through 2018 for activities authorized under this subsection. Such study shall include a review and assessment of obligations and expenditures directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, obligations and expenditures incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the obligations and expenditures incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and shall identify the agency or agencies incurring such obligations and expenditures.'';

(3) in subsection (b)—

(A) in the subsection heading, by striking ''NATIONAL'' and inserting ''ESTABLISHMENT OF SYSTEMS OF PUBLIC HEALTH '';

(B) in paragraph (1)(B), by inserting ''immunization information systems,'' after ''centers,''; and

(C) in paragraph (2)—

(i) by inserting ''develop a plan to, and'' after ''The Secretary shall''; and

(ii) by inserting ''and in a form readily usable for analytical approaches'' after ''in a secure manner''; and

(D) by amending paragraph (3) to read as follows:

''(3) STANDARDS.—

''(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in cooperation with health care providers, State, local, tribal, and territorial public health officials, and relevant Federal agencies (including the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology), shall, as necessary, adopt technical and reporting standards, including standards for interoperability as defined by section 3000, for networks under paragraph (1) and update such standards as necessary. Such standards shall be made available on the internet website of the Department of Health and Human Services, in a manner that does not compromise national security.

''(B) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this subsection and subsection (c), the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards entities.'';

(4) in subsection (c)—

(A) in paragraph (1)—

(i) by striking ''Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary'' and inserting ''The Secretary'';

(ii) by inserting '', and improve as applicable and appropriate,'' after ''shall establish'';

(iii) by striking ''of rapid'' and inserting ''of, rapid''; and

(iv) by striking ''such connectivity'' and inserting ''such interoperability'';

(B) by amending paragraph (2) to read as follows:

''(2) COORDINATION AND CONSULTATION.—In establishing and improving the network under paragraph (1) the Secretary shall—

''(A) facilitate coordination among agencies within the Department of Health and Human Services that provide, or have the potential to provide, information and data to, and analyses for, the situational awareness and biosurveillance network under paragraph (1), including coordination among relevant agencies related to health care services, the facilitation of health information exchange (including the Office of the National Coordinator for Health Information Technology), and public health emergency preparedness and response; and

''(B) consult with the Secretary of Agriculture, the Secretary of Commerce (and the Director of the National Institute of Standards and Technology), the Secretary of Defense, the Secretary of Homeland Security, and the Secretary of Veterans Affairs, and the heads of other Federal agencies, as the Secretary determines appropriate.'';

(C) in paragraph (3)—

(i) by redesignating subparagraphs (A) through (E) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (iv), as so redesignated—

(I) by inserting ''immunization information systems,'' after ''poison control,''; and

(II) by striking '' and clinical laboratories'' and inserting '', clinical laboratories, and public environmental health agencies'';

(iii) by striking ''The network'' and inserting the following:

''(A) IN GENERAL.—The network''; and

(iv) by adding at the end the following:

''(B) REVIEW.—Not later than 2 years after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 6 years thereafter, the Secretary shall conduct a review of the elements described in subparagraph (A). Such review shall include a discus-

sion of the addition of any elements pursuant to clause (v), including elements added to advancing new technologies, and identify any challenges in the incorporation of elements under subparagraph (A). The Secretary shall provide such review to the congressional committees of jurisdiction.'';

(D) in paragraph (5)—

(i) by redesignating subparagraphs (A) through (D) as clauses (i) through (iv), respectively, and adjusting the margins accordingly;

(ii) by striking ''In establishing'' and inserting the following:

''(A) IN GENERAL.—In establishing'';

(iii) by adding at the end the following:

''(B) PUBLIC MEETING.—

''(i) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals,

functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

''(ii) EXPERTS.—The public meeting shall include representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology); State, local, tribal, and territorial public health officials; stakeholders with expertise in biosurveillance and situational awareness; stakeholders with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting); and other representatives as the Secretary determines appropriate.

''(iii) TOPICS.—Such public meeting shall include a discussion of—

''(I) data elements, including minimal or essential data elements,

that are voluntarily provided for such network, which may include elements from public health and public and private health care entities, to the extent practicable;

''(II) standards and implementation specifications that may improve the collection, analysis, and interpretation of data during a public health emergency;

''(III) strategies to encourage the access, exchange, and use of information;

''(IV) considerations for State, local, tribal, and territorial capabilities and infrastructure related to data exchange and interoperability;

''(V) privacy and security protections provided at the Federal, State, local, tribal, and territorial levels, and by nongovernmental stakeholders; and

''(VI) opportunities for the incorporation of innovative technologies to improve the network.''; and

(iv) in subparagraph (A), as so designated by clause (ii)—

(I) in clause (i), as so redesignated—

(aa) by striking ''as determined'' and inserting ''as adopted''; and

(bb) by inserting ''and the National Institute of Standards and Technology'' after ''Office of the National Coordinator for Health Information Technology'';

(II) in clause (iii), as so redesignated, by striking ''; and'' and inserting a semicolon;

(III) in clause (iv), as so redesignated, by striking the period and inserting ''; and''; and

(IV) by adding at the end the following:

''(v) pilot test standards and implementation specifications, consistent with the process described in section 3002(b)(3)(C), which State, local, tribal, and territorial public health entities may

utilize, on a voluntary basis, as a part of the network.'';

(E) by redesignating paragraph (6) as paragraph (7);

(F) by inserting after paragraph (5) the following:

''(6) STRATEGY AND IMPLEMENTATION PLAN.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall submit to the congressional committees of jurisdiction a coordinated strategy and an accompanying implementation plan that—

''(i) is informed by the public meeting under paragraph (5)(B);

''(ii) includes a review and assessment of existing capabilities of the network and related infrastructure, including input provided by the public meeting under paragraph (5)(B);

''(iii) identifies and demonstrates the measurable steps the Secretary will carry out to—

''(I) develop, implement, and evaluate the network described in paragraph (1), utilizing elements described in paragraph (3)(A);

''(II) modernize and enhance biosurveillance activities, including strategies to include innovative technologies and analytical approaches (including prediction and forecasting for pandemics and all-hazards) from public and private entities;

''(III) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services, including the identification of methods to improve accountability, better utilize resources and workforce capabilities, and incorporate innovative technologies within and across agencies; and

''(IV) test and evaluate capabilities of the interoperable network of

systems to improve situational awareness and biosurveillance capabilities;

''(iv) includes performance measures and the metrics by which performance measures will be assessed with respect to the measurable steps under clause (iii); and

''(v) establishes dates by which each measurable step under clause (iii) will be implemented.''.

''(B) ANNUAL BUDGET PLAN.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and on an annual basis thereafter, in accordance with the strategy and implementation plan under this paragraph, the Secretary shall, taking into account recommendations provided by the National Biodefense Science Board, develop a budget plan based on the strategy and implementation plan under this section. Such budget plan shall include—

''(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situa-

tional awareness and biosurveillance network under paragraph (1);

''(ii) estimates of costs and resources needed to establish and improve the network under paragraph (1) according to the strategy and implementation plan under subparagraph (A);

''(iii) the identification of gaps and inefficiencies in nationwide public health situational awareness and biosurveillance capabilities, resources, and authorities needed to address such gaps; and

''(iv) a strategy to minimize and address such gaps and improve inefficiencies.'';

(G) in paragraph (7), as so redesignated—

(i) in subparagraph (A), by inserting ''(taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health)'' after ''human health'';

(ii) in subparagraph (B)—

(I) by inserting ''and gaps in surveillance programs'' after ''surveillance programs''; and

(II) by striking ''; and'' and inserting a semicolon;

(iii) in subparagraph (C)—

(I) by inserting '', animal health organizations related to zoonotic disease,'' after ''health care entities''; and

(II) by striking the period and inserting ''; and''; and

(iv) by adding at the end the following:

''(D) provide recommendations to the Secretary on policies and procedures to complete the steps described in this paragraph in a manner that is consistent with section 2802.''; and

(H) by adding at the end the following:

''(8) SITUATIONAL AWARENESS AND BIOSURVEILLANCE AS A NATIONAL SECURITY PRIORITY.—The Secretary, on a periodic basis as applicable and appropriate, shall meet with the Director of National Intelligence to inform the development

and capabilities of the nationwide public health situational awareness and biosurveillance network.'';

(5) in subsection (d)—

(A) in paragraph (1)—

(i) by inserting ''environmental health agencies,'' after ''public health agencies,''; and

(ii) by inserting ''immunization programs,'' after ''poison control centers,''; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking ''and'' at the end;

(ii) in subparagraph (C), by striking the period and inserting ''; and''; and

(iii) by adding after subparagraph (C) the following:

''(D) an implementation plan that may include measurable steps to achieve the purposes described in paragraph (1).''; and

(C) by striking paragraph (5) and inserting the following:

''(5) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States, localities, tribes, and territories or a consortium of States, lo-

calities, tribes, and territories receiving an award under this subsection regarding interoperability and the technical standards set forth by the Secretary.'';

(6) by redesignating subsections (f) and (g) as subsections (i) and (j), respectively; and

(7) by inserting after subsection (e) the following:

''(f) PERSONNEL AUTHORITIES.—

''(1) SPECIALLY QUALIFIED PERSONNEL.—In addition to any other personnel authorities, to carry out subsection (b) and subsection (c), the Secretary may—

''(A) appoint highly qualified individuals to scientific or professional positions at the Centers for Disease Control and Prevention, not to exceed 30 such employees at any time (specific to positions authorized by this subsection), with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting), and other related scientific or technical fields; and

''(B) compensate individuals appointed under subparagraph (A) in the same manner

and subject to the same terms and conditions in which individuals appointed under 9903 of title 5, United States Code, are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates.

''(2) LIMITATIONS.—The Secretary shall exercise the authority under paragraph (1) in a manner that is consistent with the limitations described in section 319F–1(e)(2).

''(g) TIMELINE.—The Secretary shall accomplish the purposes under subsections (b) and (c) no later than September 30, 2023, and shall provide a justification to the congressional committees of jurisdiction for any missed or delayed implementation of measurable steps identified under subsection (c)(6)(A)(iii).

''(h) INDEPENDENT EVALUATION.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the congressional committees of jurisdiction a report concerning the activities conducted under subsections (b) and (c), and provide recommendations, as

applicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Subsection (i) of section 319D (42 U.S.C. 247d–4), as redesignated by subsection (a)(6), is amended by striking ''$138,300,000 for each of fiscal years 2014 through 2018'' and inserting ''$161,800,000 for each of fiscal years 2019 through 2023''.

Page 72, line 10, insert at the end ''and''.

Page 72, line 12, strike ''; and'' and insert a period.

Page 72, strike lines 13 through 14.

Page 72, line 22, strike ''Not later than 60 days'' and insert ''As soon as possible, but not later than 6 months''.

Page 73, after line 7, insert the following:

(2) ARRAY OF EXPERTS.—The arrangement under paragraph (1) shall require the National Academy (or other appropriate entity) to engage an array of experts, including appropriate government experts, when conducting the evaluation under paragraph (1).

Page 74, line 25, strike ''18 months'' and insert ''3 years''.

Page 81, line 14, through page 82, line 6, strike paragraph (2) (and make such conforming changes as may be necessary).

Page 82, after line 6, insert the following:

(b) EVALUATION OF OBSTACLES TO RAPID DELIVERY OF MEDICAL COUNTERMEASURES.—Section 319F–2(a) of the Public Health Service Act (247d–6b(a)) is amended by adding at the end the following:

''(4) RAPID DELIVERY STUDY.—The Assistant Secretary for Preparedness and Response may conduct a study on issues that have the potential to adversely affect the handling and rapid delivery of safe, secure, or sterile medical countermeasures to individuals who are at risk during public health emergencies occurring in the United States.

''(5) REPORT TO CONGRESS.—If the Assistant Secretary for Preparedness and Response conducts the study authorized under paragraph (4), the Assistant Secretary, not later than 18 months after the date on which such study is completed, shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate containing the findings of such study.''.

Page 82, line 19, after ''Representatives'' insert ''that a determination has been made pursuant to subparagraph (A) or (B)''.

Page 83, after line 21, insert the following (and make such conforming changes as may be necessary):

(a) UPDATING DEFINITION OF OTHER TRANSACTIONS.—Section 319L(a)(3) of the Public Health Service Act (42 U.S.C. 247d–7e(a)(3)) is amended by striking '', such as the Secretary of Defense may enter into under section 2371 of title 10, United States Code''.

Page 87, line 8, insert ''advanced'' before ''research and development''.

Page 87, lines 24 and 25, insert ''advanced'' before ''research and development''.

Page 87, line 25, insert ''activities for qualified pandemic or epidemic products'' after ''development''.

Page 90, line 8, strike ''300h–1'' and insert ''300hh–1''.

Page 91, lines 9 through 10, strike ''ensuring the ability of'' and insert ''coordinating preparedness, response, and recovery activities within''.

Page 92, after line 15, insert the following:

(d) REGULATORY MANAGEMENT PLANS.—Section 565(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb–4(f)) is amended—

(1) by redesignating paragraphs (3) through (6) as paragraphs (4) through (7), respectively;

(2) by inserting after paragraph (2) the following:

''(3) PUBLICATION.—The Secretary shall make available on the internet website of the Food and Drug Administration information regarding regulatory management plans, including—

''(A) the process by which an applicant may submit a request for a regulatory management plan;

''(B) the timeframe by which the Secretary is required to respond to such request;

''(C) the information required for the submission of such request;

''(D) a description of the types of development milestones and performance targets that could be discussed and included in such plans; and

''(E) contact information for beginning the regulatory management plan process.'';

(3) in paragraph (6), as so redesignated, in the matter preceding subparagraph (A)—

(A) by striking ''paragraph (4)(A)'' and inserting ''paragraph (5)(A)''; and

(B) by striking ''paragraph (4)(B)'' and inserting ''paragraph (5)(B)''; and

(4) in paragraph (7)(A), as so redesignated, by striking ''paragraph (3)(A)'' and inserting ''paragraph (4)(A)''.

(e) ANIMAL RULE REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the application of the requirements under section 565(d) of the of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d)) (referred to in this section as the ''animal rule'') as a component of medical countermeasure advanced development under the Biomedical Advanced Research and Development Authority and regulatory review by the Food and Drug Administration. In conducting such study, the Comptroller General shall examine the following:

(A) The extent to which advanced development and review of a medical countermeasure are coordinated between the Biomedical Advanced Research and Development Authority

and the Food and Drug Administration, including activities to facilitate appropriate and efficient design of studies to support approval, licensure, and authorization under the animal rule, consistent with the recommendations in the animal rule guidance, issued pursuant to section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)) and entitled ''Product Development Under the Animal Rule Guidance for Industry'' (issued in October 2015), to resolve discrepancies in the design of adequate and well-controlled efficacy studies conducted in animal models related to the provision of substantial evidence of effectiveness for the product approved, licensed, or authorized under the animal rule.

(B) The consistency of the application of the animal rule among and between review divisions within the Food and Drug Administration.

(C) The flexibilities pursuant to the animal rule to address variations in countermeasure development and review processes, including the extent to which qualified animal models are adopted and used within the Food and Drug

Administration in regulatory decisionmaking with respect to medical countermeasures.

(D) The extent to which the guidance issued under section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled, ''Product Development Under the Animal Rule Guidance for Industry'' (issued in October 2015), has assisted in achieving the purposes described in subparagraphs (A), (B), and (C).

(2) CONSULTATIONS.—In conducting the study under paragraph (1), the Comptroller General of the United States shall consult with—

(A) the Federal agencies responsible for advancing, reviewing, and procuring medical countermeasures, including the Office of the Assistant Secretary for Preparedness and Response, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, and the Department of Defense;

(B) manufacturers involved in the research and development of medical countermeasures to address biological, chemical, radiological, and nuclear threats; and

(C) other biodefense stakeholders, as applicable.

(3) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under paragraph (1) and recommendations to improve the application and consistency of the requirements under subsections (c) and (d) of section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) to support and expedite the research and development of medical countermeasures, as applicable.

(4) PROTECTION OF NATIONAL SECURITY.—The Comptroller General of the United States shall conduct the study and issue the assessment and report under this subsection in a manner that does not compromise national security.

Page 92, after section 402, as amended above, insert the following new section (and make such conforming changes as may be necessary):

SEC. 403. MEDICAL COUNTERMEASURE MASTER FILES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 565A the following:

"SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.

"(a) APPLICABILITY OF REFERENCE.—

"(1) IN GENERAL.—A person may submit data and information in a master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to reference the master file. Such data and information shall be available for reference by the master file holder or a person authorized by the master file holder only in accordance with applicable privacy and confidentiality protocols and regulations.

"(2) LIMITATION.—Notwithstanding paragraph (1), a person may not reference, or authorize another person to reference, data or information to support a medical countermeasure submission to the extent such data or information is in the master file

for an application for conditional approval under section 571.

''(b) MEDICAL COUNTERMEASURE MASTER FILE CONTENT.—

''(1) IN GENERAL.—A medical countermeasure master file may include data and information to support—

''(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

''(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

''(2) REQUIRED UPDATES.—The Secretary may require, as appropriate, that the master file holder ensure that the contents of such master file are updated during the time such master file is referenced for a medical countermeasure submission.

''(c) SPONSOR REFERENCE.—

''(1) IN GENERAL.—Each incorporation of data or information contained in a master file by ref-

erence shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of such data or information without necessitating resubmission of such data or information. Master files shall be submitted in an electronic format in accordance with section 745A and as specified in applicable guidance.

''(2) REFERENCE BY A MASTER FILE HOLDER.—A master file holder that is the sponsor of a medical countermeasure submission shall notify the Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

''(3) REFERENCE BY AN AUTHORIZED PERSON.—A sponsor of a medical countermeasure submission may, where the Secretary determines appropriate, incorporate by reference all or part of the contents of a medical countermeasure master file, if the master file holder authorizes the incorporation in writing.

''(d) ACKNOWLEDGMENT OF MASTER FILE BY THE SECRETARY.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified data or information within a master file and the purposes for which

such data or information was incorporated by reference if the Secretary has reviewed and relied upon such specified data or information to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

''(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(1) alter the authority of the Secretary to approve, license, classify, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018), including the standards of evidence, and applicable conditions, for approval under the applicable Act; or

''(2) alter the authority of the Secretary under this Act or the Public Health Service Act to deter-

mine the types of data or information previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under section 505(i), 505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571, 520(g), 515(c), 513(f)(2), or 510(k) of this Act, or subsection (a) or (k) of section 351 of the Public Health Service Act, including a supplement or amendment to any such submission, and the requirements associated with such reference.

''(f) DEFINITIONS.—In this section:

''(1) The term 'master file holder' means a person who submits data and information to the Secretary with the intent to reference or authorize to reference such data or information to support a medical countermeasure submission, as described in subsection (a)(1).

''(2) The term 'medical countermeasure submission' means an investigational new drug application under section 505(i), a new drug application under section 505(b), or an abbreviated new drug application under section 505(j) of this Act, a biological product license application under section 351(a) of the Public Health Service Act or a biosimilar biologi-

cal product license application under section 351(k) of the Public Health Service Act, a new animal drug application under section 512(b)(1) or abbreviated new animal drug application under section 512(b)(2), an application for conditional approval of a new animal drug under 571, an investigational device application under section 520(g), an application with respect to a device under section 515(c), a request for classification of a device under section 513(f)(2), a notification with respect to a device under section 510(k), or request for an emergency use authorization under section 564 to support—

''(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

''(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

''(3) The terms 'qualified countermeasure', 'security countermeasure', and 'qualified pandemic or epidemic product' have the meanings given such terms in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act.''.

(b) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary for Preparedness and Response, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products, and stakeholders developing technologies to assist in the development of such countermeasures with respect to how the Food and Drug Administration can advance the use of tools and technologies to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through the reliance on cross-referenced data and information contained within master files and submissions previously submitted to the Secretary as set forth in section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) GUIDANCE.—Not later than 2 years after the after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall publish draft guidance about how reliance on cross-referenced data and information contained within master

files under section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), or submissions otherwise submitted to the Secretary may be used for specific tools or technologies (including platform technologies) that have the potential to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, qualified pandemic or epidemic products. The Secretary, acting through the Commissioner of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act.

Page 104, line 2, insert ''Presidential'' before ''Advisory Council on Combating Antibiotic-Resistant Bacteria''.

Page 106, lines 5 through 6, strike ''Transatlantic Taskforce on Antimicrobial Resistence'' and insert ''Antimicrobial Resistance Task Force established under 319E(a) (commonly referred to as the 'Combatting Antibiotic-Resistant Bacteria Task Force')''.

At the end of title IV, add the following:

SEC. 408. REVIEW OF THE BENEFITS OF GENOMIC ENGINEERING TECHNOLOGIES AND THEIR POTENTIAL ROLE IN NATIONAL SECURITY.

(a) MEETING.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall convene a meeting to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security. Such meeting shall be held in a manner that does not compromise national security.

(2) ATTENDEES.—The attendees of the meeting under paragraph (1)—

(A) shall include—

(i) representatives from the Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration; and

(ii) representatives from academic, private, and non-profit entities with expertise in genome engineering technologies, biopharmaceuticals, medicine, or biodefense, and other relevant stakeholders; and

(B) may include—

(i) other representatives from the Department of Health and Human Services, as the Secretary determines appropriate; and

(ii) representatives from the Department of Homeland Security, the Department of Defense, the Department of Agriculture, and other departments, as the Secretary may request for the meeting.

(3) TOPICS.—The meeting under paragraph (1) shall include a discussion of—

(A) the current state of the science of genomic engineering technologies related to national health security, including—

(i) medical countermeasure development, including potential efficiencies in the development pathway and detection technologies; and

(ii) the international and domestic regulation of products utilizing genome editing technologies; and

(B) national security implications, including—

(i) capabilities of the United States to leverage genomic engineering technologies

as a part of the medical countermeasure enterprise, including current applicable research, development, and application efforts underway within the Department of Defense;

(ii) the potential for state and non-state actors to utilize genomic engineering technologies as a national health security threat; and

(iii) security measures to monitor and assess the potential threat of genomic engineering technologies and related technologies.

(b) REPORT.—Not later than 270 days after the meeting described in subsection (a) is held, the Assistant Secretary for Preparedness and Response shall issue a report to the congressional committees of jurisdiction on the topics discussed at such meeting, and provide recommendations, as applicable, to utilize innovations in genomic engineering (including genome editing) and related technologies as a part of preparedness and response activities to advance national health security. Such report shall be issued in a manner that does not compromise national security.